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schottlander

510(K) Notification for Matchmaker/Propaque Porcelain

7. 510(K) Summary of the safety and effectiveness information upon which the substantial equivalence determination for Matchmaker/Propaque porcelains are based

Name of contact person:	Mr B D Schottlander
Date that Summary was prepared	16 February 1996
Trade name	Matchmaker/Propaque porcelains
Common name	Bonding porcelain or metallo ceramic
Classification name	872.6660-porcelain powder for clinical use

The legally marketed device to which we are claiming equivalence is called **Creation**.

The device is a feldspathic porcelain supplied for fusing to a metal sub-structure to form an aesthetic restoration which is then fitted as a crown or bridge.

Comparison to predicate device.

Chemical Similarities

Both products are feldspathic porcelains conforming to ISO 9693:1991 and are used in dentistry for fusing to a metal frame work to form an enamel porcelain layer. Both products are supplied with different layers ie; opaque, dentine, enamel etc. in order to replicate different colour layers in a natural tooth. Both products fall within the same class and part numbers. Both products are claimed on the labelling and directions for use to have essentially the same properties and usage.

Application Similarities

Both products are supplied as a powder for mixing together with a liquid to form a paste or as a pre-mixed paste. Both products are supplied with different layers ie; opaque, dentine, enamel etc. in order to replicate different colour layers in a natural tooth and these layers are built up and fired in a furnace in the same order and at similar temperatures (see also below).

Performance similarities.

Both products have essentially the same firing characteristics including low temperature for insertion into the furnace, drying time, final temperature and requirement for vacuum. Both products are manufactured to conform to ISO 9693:1991 Dental Ceramic Fused to Metal Restorative Material. This standard specifies performance criteria such as flexural strength, chemical solubility, fired porosity, coefficient of expansion, glass transition temperature and metallo-ceramic bond characterisation.

From the above information it is concluded that Matchmaker/Propaque porcelain possess substantial equivalence to the predicate device.